RANDOX

DEC - 1 2011

K112337

510(k) Summary

Safety and Effectiveness as Required by 21 CFR 807.92

Manufacturer and Submitter

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Device Name

Trade Name: Randox Liquid Immunoassay Premium Controls Levels 1, 2 and 3, and Tri Level

Common Name: Liquid Immunoassay Premium Controls Levels 1, 2 and 3, and Tri Level

Classification: Multianalyte Controls, All kinds (Assayed and Unassayed)

Product Code: JJY

Date of Summary Preparation

22nd November 2011

Predicate Devices

Bio-Rad Liquichek Immunoassay Plus Controls Levels 1, 2 and 3

RANDOX

Device Description

Randox Liquid Immunoassay Premium Controls are manufactured at three levels, Level 1, Level 2 and Level 3, as well as a Tri Level product. The analyte concentrations in each of the three levels have been chosen to span a range that includes the chemically significant or medical decision level(s). The analyte concentrations have been reviewed by a panel of experts to ensure that the concentrations are clinically relevant for use in routine hospital laboratories.

Intended Use

The Randox Liquid Immunoassay Premium Controls, Level 1, Level 2, Level 3 and Tri Level are liquid controls developed for use in the quality control of quantitative assays stated in the package insert.

Similarity to Predicate Device

- Both are assayed quality control serums.
- Both are intended to monitor the precision of laboratory testing procedures for the analytes named in the product insert.
- Both are in vitro diagnostic medical devices.
- Both devices are in liquid format and manufactured from human serum.

Stability

Serum is stable for 7 days (when thawed) at +2 - +8°C. To assess the shelf life stability claims, real time stability studies of the device have been carried out. A shelf life stability claim of 12 months has been noted for the device, with 2 lots having achieved at least this claim, and tests ongoing to obtain real time data for 24 months.

Conclusion

Testing results indicate that the proposed device is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Randox Laboratories Limited
c/o Pauline Armstrong
55 Diamond Road
Crumlin Antrim
United Kingdom BT29 4QY

DEC - 1 2011

Re: k112337
Trade/Device Name: Randox Liquid Immunoassay Premium Controls, Level 1, level 2, Level 3 and Tri Level
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: October 4, 2011
Received: October 6, 2011

Dear Dr. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~Unknown~~ K112337

Device Name: Randox Liquid Immunoassay Premium Controls Level 1, Level 2, Level 3 and Tri-Level

Indication For Use:

The Randox Liquid Immunoassay Premium Controls Level 1, Level 2, Level 3 and Tri level are liquid controls developed for use in the quality control of the quantitative assays stated on the package insert. This in vitro diagnostic device is intended for prescription use only.

Prescription Use ✓ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

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